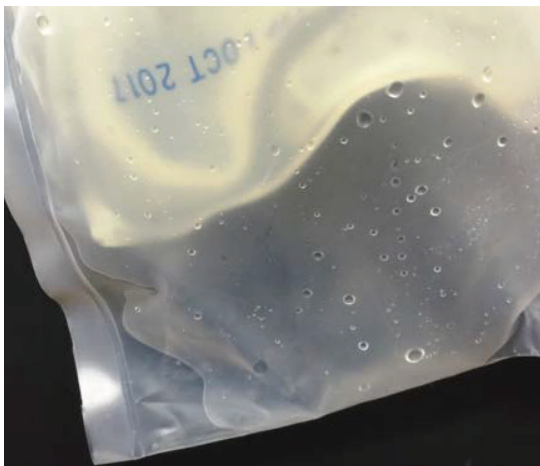


Observing Moisture Inside a Protective Overwrap

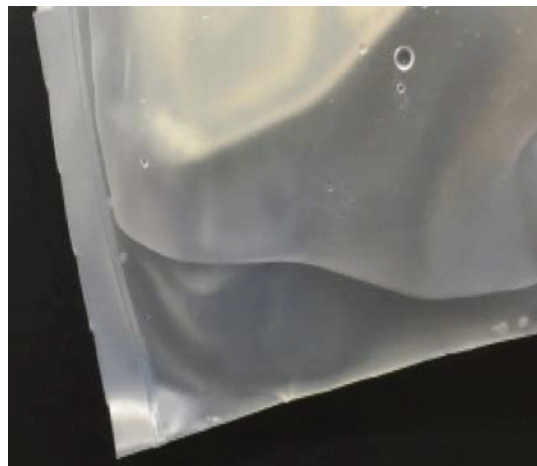
Otsuka ICU Medical LLC packages parenteral drug products in flexible plastic containers referred to as primary bags. All primary bags go through a rinse cycle prior to pouching inside a protective overwrap which is then followed by sterilization. Differences in moisture permeability between the primary bag and overwrap, as well as changes in storage temperatures, may cause moisture to condense in the overwrap. As a result, some residual moisture may be visible between the primary bag and the overwrap. The residual moisture between the overwrap and the primary bag is a normal occurrence and does not affect product quality or safety.

How much moisture inside the protective overwrap is acceptable?

Moisture inside the protective overwrap from the rinse cycle, sterilization process, and differences in permeability between the primary bag and overwrap is normal. A normal range of moisture can vary from 1 mL to 3 mL of fluid. Beyond this range, excessive moisture in a bag is unacceptable, see below:



Normal moisture



Excessive moisture

How can I determine if the moisture level in the protective overwrap is acceptable or due to a leaking bag?

To distinguish between acceptable moisture levels in the overwrap and a leaking primary bag:

- Remove the protective overwrap, and check for minute leaks by firmly squeezing the bag. Keep the infusion bags in the overwrap until ready to use.
- If leaks are detected, discard the solution, as sterility may be impaired.

For medical inquiries or to report a suspected side effect, adverse reaction or concern about the quality of a IV Solutions, please contact us at 866-829-9025.

Manufactured by:
Otsuka ICU Medical LLC

Distributed by:

icumedical